Informed Consent Standardization and Simplification Projects
Updated December 2007

The caBIG™ Data Sharing and Intellectual Capital (DSIC) Workspace has developed model forms to facilitate appropriate exchange of human specimens and data for cancer research. These are available at https://cabig.nci.nih.gov/working_groups/DSIC_SLWG/Documents/. Numerous efforts are underway across the country to further simplify informed consent documents. Many, but not all, of these initiatives focus on interventional clinical trials, but the developed materials are helpful in designing and implementing useful forms and processes.

1. Agency for Healthcare Research and Quality (AHRQ)

AHRQ has developed and is piloting an "Informed Consent Toolkit," consisting of sample documents for Common Rule informed consent alone, HIPAA authorization alone, and combined; plus guidance promoting a high-quality informed consent process; and a series of case studies describing circumstances where verbal consent may be a permissible alternative to written consent. The toolkit is geared toward health services research studies but many of its features can be helpful in designing consent forms for clinical trials and research databases and registries. The Toolkit has not yet been made publicly available. Cindy Brach, MPP, of the Center for Delivery, Organization, and Markets leads this effort.

2. Association of Academic Medical Centers (AAMC)

Current project to "create informed consent documents that are approachable, readable, and brief." A presentation describing the project is available at http://www.aamc.org/research/clinicalresearch/hdickler-sachrp07.pdf. A summary of progress to date is available at http://www.aamc.org/research/clinicalresearch/hdickler-mtgsumrpt53007.pdf.

3. Children's Oncology Group (COG)

Maura O'Leary described a COG initiative to simplify informed consent documents to the AAMC task force, which was summarized as follows:

> A Task Force began work in 2004 to address issues that included length (commonly over 20 pages), complexity and difficult language (grade 14), failure to distinguish standard of care from research, and lack of consistency. The task force used an iterative consensus process involving the COG membership, the Pediatric Central IRB, local IRBs and the patient advocacy committee. New informed consent document templates were developed for Phases I, II, and III which focused on research and were developed as part of a larger process that utilized a host of educational supplemental materials (handbooks, websites) and appendices (standard treatment, diagrams, risk table, certificate of confidentiality).

The consents use simple language (Junior High level), one thought per sentence, short paragraphs, a template table of standard treatments in an attachment, and short, simple templates for concepts used repeatedly (randomization, dose escalation, and standard therapy phrases like induction and consolidation). It is found to be more efficient to use a small group to create all the consents because this improved consistency and also fostered improved consent writing skills over time. This also helped to prevent template "creep".

4. Group Health Center for Health Studies/PRISM

Group Health's Center for Health Studies has developed a "Readability Toolkit" as part of its Project to Review and Improve Study Materials (PRSIM). This Toolkit is designed to assist researchers in developing study materials that research participants can easily read and understand. Among other features, the Toolkit includes easy-to-read template language for common topics in consent forms such as randomization and voluntary participation.

5. National Cancer Institute (NCI)

In the late 1990s, NCI and the Office of Protection from Research Risks (OPRR – now the Office for Human Research Protections) initiated a joint project that resulted in a "simplified" consent form for cancer clinical trials, issued in 1998. See http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/ for background, recommendations, templates, and supplementary materials. Templates include addenda for related quality-of-life (QOL) and tissue research. See http://www.nih.gov/news/pr/oct98/nci-22.htm for the original press release.

Also in 1998, the National Action Plan on Breast Cancer launched a project that resulted in a standardized tissue consent form, patient information sheet, and IRB principles discussion. The current sample form and patient information sheet are available at http://www.cancerdiagnosis.nci.nih.gov/specimens/legal.htm#3b or on the NAPBC website at http://www.4women.gov/napbc/catalog.wci/napbc/consent.htm and http://www.4women.gov/napbc/catalog.wci/napbc/q&a.htm. Background on the initiative is available at http://www.4women.gov/napbc/catalog.wci/napbc/sunset2.htm.

More recently, NCI has published a "Guide to Understanding Informed Consent," available at http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide/allpages, first posted in 2001 and last reviewed in 2005. The guide provides useful information for patients considering participating in cancer clinical trials. See also Coalition of Cancer Cooperative Groups, "About Clinical Trials: Informed Consent," available at http://www.cancertrialshelp.org/patientsCaregivers/informedConsent.jsp.

Currently, the Cooperative Group Banking Committee ("GBC") is working on updated templates for tissue banking and associated research.

6. Secretary's Advisory Committee on Human Research Protections (SACHRP)

SACHRP has convened a Panel on Informed Consent. Panel activities are expected to result in recommendations on improving the informed consent form and process. A copy of the Panel's charge is available at http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-07/present/Informedconsentpanel.doc. Presentations made to the panel in July 2007 are available at http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-07/present.htm.

Additional References

Davis TC, Holcombe RF, Berkel HJ, Pramanik S, Divers SG, "Informed Consent for Clinical Trials: a Comparative Study of Standard Versus Simplified Forms," JNCI 90:9 (May 6, 1998), available at http://jnci.oxfordjournals.org/cgi/reprint/jnci%3b90/9/668.pdf?ck=nck

Paasche-Orlow MK, Taylor HA, Brancati FL, "Readability Standards for Informed-Consent Forms as Compared with Actual Readability," NEJM 348: 721-26 (Feb. 20, 2003), available at http://content.nejm.org/cgi/content/full/348/8/721.

Tait AR, Voepel-Lewis T, Malviya S, Philipson SJ, "Improving the Readability and Processability of a Pediatric Informed Consent Document: Effects on Parents' Understanding," Arch. Pediatr. Adolesc. Med. 159:4; 347 (April 2005), available at http://archpedi.ama-assn.org/cgi/reprint/159/4/347.pdf

Links

CTEP Lay Term Mapping Document (AEs):
http://ctep.cancer.gov/forms/ctcae_laypublish.xls

NCI CTSA Website: http://crpac.od.nih.gov/issue_Informed_Consent.asp

NCI Materials: http://www.cancer.gov/clinicaltrials/digestpage/protecting-participants

NCI Model Tissue Consent:
http://www.cancerdiagnosis.nci.nih.gov/specimens/legal.htm#3b

ORI Resource List:
http://ori.dhhs.gov/documents/NIHResourcesonInformedConsentAnnotated6-29-07.doc

TCGA Model Consent (Prospective Studies):
http://cancergenome.nih.gov/components/TCGA-Model_Informed_Consent_Form_Prospective.pdf

TCGA Model Consent (Retrospective Studies):
http://cancergenome.nih.gov/components/TCGA-Model_Informed_Consent_Form_Retrospective.pdf

University of Michigan IRBMED: http://www.med.umich.edu/irbmed/guidance/tips.htm